K013718

JAN 8 2002

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: GYNEMESH PROLENE Soft (Polypropylene) Mesh

PREDICATE DEVICE NAME: PROLENE Soft (Polypropylene) Mesh, PROLENE* (Polypropylene) Mesh and MERSILENE* Mesh

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510(k) SUMMARY

Device Description

GYNEMESH PROLENE Soft Mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh affords excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE Mesh. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.

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510(k) SUMMARY, Continued

Description (continued)	GYNEMESH PROLENE Soft Mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaption to various stresses encountered in the body.
Intended Use	This mesh is intended for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
Indications Statement	This mesh is used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
Technological Characteristics	For technological characteristics, the values are the same as PROLENE Soft Mesh and are less than those of PROLENE Mesh, but greater than those of MERSILENE Mesh do. GYNEMESH PROLENE Soft Mesh, PROLENE Soft Mesh and PROLENE Mesh are constructed of polypropylene fibers. GYNEMESH PROLENE Soft M and PROLENE Soft Mesh offers a 50% more flexible monofilament mesh.
Performance Data	Nonclinical laboratory testing was not performed as there is no change to the clinical intended use as compared to the two predicate devices. Sufficient bench testing was conducted in accordance with the FDA guidance document ""Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh." Published clinical data on the use of PROLENE Mesh and MERSILENE mesh was submitted to support the used of these materials as reinforcing or bridging materials in fascial deficiencies of the pelvic wall.

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Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory R. Jones
Director, GYNECARE QA/RA
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

November 6, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Mr. Gregory R. Jones
Director, GYNECARE RA/QA
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876

Re: K013718
Trade/Device Name: GYNEMESH PROLENE Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Codes: FTL, FTM
Dated: November 06, 2001
Received: November 08, 2001

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K013718

Device Name: GYNEMESH PROLENE* Soft (Polypropylene) Mesh

Indications for Use: GYNEMESH PROLENE Soft (Polypropylene) Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

NPO for CDRH

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013718

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The Counter Use _____

(Optional Format 1-2-9G)